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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	760-35 CIP	6660

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/002,521	Applicant(s) GIRTON ET AL.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11-16 and 21-24 is/are pending in the application.
4a) Of the above claim(s) 4 and 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2004 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 21-24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk (US 4,657,544, cited by applicant in IDS). Referring to claims 1 and 3, Pinchuk discloses a medical device/vascular graft (10; col.1, lines 6-11) comprising an implantable tubular extrudate (col.2, lines 58-61; col.4, lines 45-48) comprising an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure (graft 10 comprises PTFE, polytetrafluoroethylene, col.4, lines 4-10), the matrix having distributed therein discrete domains of an extractable polymeric material (salt crystals, although not polymeric, they

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are eventually extracted, and are not present in the end product), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric material (salt) is extracted from the matrix to create pores (16) in the tubular extrudate ("Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir.1985), extraction of polymeric material is a product by process limitations, the end product is a PTFE porous extrudate; Pinchuk discloses extracting salt to create pores, leaving a porous PTFE extrudate, the same end product, col.4, lines 48-52; because the applicants polymeric material is extracted, whether it was polymeric or not, does not matter. The salt that is extracted in Pinchuk, forms the same end product as extracting polymeric materials would, a porous structure comprising PTFE, see MPEP 2113) which upon implantation permit tissue ingrowth (col.1, lines 10-11; col.3, lines 57-64).

Referring to claim 21, Pinchuk discloses an extractable polymeric material to comprise silicone (this is a product-by-process limitation, the silicone is claimed to be extracted, therefore not present in the end product and Pinchuk's salt crystals create the same porous end product).

Referring to claim 22, Pinchuk discloses a medical device (10) comprising a tubular extrudate (col.2, lines 58-61; col.4, lines 45-48) comprising an interpenetrating network comprising a non-expanded PTFE matrix having no node and fibril structure (graft 10 comprises PTFE, polytetrafluorethylene, col.4, lines 4-10), the matrix having distributed therein discrete

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domains of an extractable polymeric material (salt crystals, although not polymeric, they are eventually extracted, and are not present in the end product), the extractable polymeric material being particulate having a particle size of about 5-100 microns (col.3, lines 38-42; col.6, lines 14-17), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric material is extracted from the matrix to create pores (16) corresponding to the particle size in the tubular extrudate ("Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir.1985), extraction of polymeric material is a product by process limitations, the end product is a PTFE porous extrudate; Pinchuk discloses extracting salt to create pores, leaving a porous PTFE extrudate, the same end product, col.4, lines 48-52; because the applicants polymeric material is extracted, whether it was polymeric or not, does not matter. The salt that is extracted in Pinchuk, forms the same end product as extracting polymeric materials would, a porous structure comprising PTFE, see MPEP 2113) which upon implantation permit tissue ingrowth (col.1, lines 10-11; col.3, lines 57-64).

Referring to claim 23, Pinchuk discloses an implantable, non-expanded, porous PTFE extrudate (10) comprising a tubular extrudate (col.2, lines 58-61; col.4, lines 45-48) comprising non-expanded PTFE having no node and fibril structure (graft 10 comprises PTFE, polytetrafluorethylene, col.4, lines 4-10) and a plurality of pores (16) distributed throughout the non-expanded PTFE (fig.1), the pores (16) having a shape defined by an extracted polymeric

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material (shape shown in fig.2), the polymeric material being in a form selected from the group consisting of a gel, liquid and flowable material (this is a product-by-process limitation, see above; the salt crystals of Pinchuk may have the shape of liquid or gel droplets or clumps, therefore, the same end product results, whether the beginning product has liquid, gels, or salt. It is also noted to the applicant, that upon leaching, the salt of Pinchuk is dissolved and turned into a liquid).

Referring to claim 24, Pinchuk discloses an implantable PTFE extrudate (10) comprising a non-expanded PTFE resin having no node and fibril structure (col.4, lines 4-9), and a particulate polymeric component (salt, a polymer is not required, since this is a product-by-process limitation and the polymeric component is extracted and not present in the end product upon implantation) which is incompatible with the non-expanded PTFE resin, wherein discrete domains of the polymeric component are distributed through out the non-expanded PTFE resin and are extractable therefrom to create pores (16) in the PTFE resin which upon implantation permit tissue ingrowth (col.1, lines 10-11; col.3, lines 57-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk (US 4,657,544, cited by applicant in IDS) in view of Dereume et al. (USPN 5,639,278, cited in previous office action). Pinchuk discloses a medical device (vascular graft, 10) comprising a

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tubular extrudate (col.4, lines 45-49), which comprises a non-expanded porous (16) PTFE matrix (col.4, lines 4-10). Pinchuk does not teach however, a stent combined with the graft. Dereume teaches in the same field of medical devices, combining an axially positioned stent (22) within a graft (23 or 24), in order to provide increased support on the graft to better hold open the vessel (col.2, line 64-col.3, line 4; col.3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent with a graft, with Pinchuk's specific type of graft, in order to provide a medical device that more properly supports an artery or a vein.

Claims 1, 3, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilla et al. (US 6,540,780 B1, cited in previous office action). Referring to all claims, Zilla discloses an implantable medical device/vascular graft (col.1, lines 11-16) comprising a polymeric tubular extrudate (18, 30; col.4, lines 20-28; col.7, lines 46-55; col.3, lines 19-22) having distributed therein discrete domains of an extractable polymeric material (14, 36; particles, liquids, and gels all are disclosed by Zilla as extractable materials, fibers, fillers; col.3, lines 45-58; col.4, lines 55-67; col.6, lines 9-16, 61-63), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric material is extracted from the extrudate matrix to create pores (col.3, lines 46-57; col.4, lines 55-67; col.8, lines 62-67) which upon implantation permit tissue ingrowth. Zilla discloses a medical device/vascular graft substantially as claimed, however discloses use of polymers such as polyurethane for the extrudate instead of non-expanded unfibrillated PTFE. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an extrudate of PTFE (a

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commonly used material for vascular grafts) instead of polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER